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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAWES, PILI ASABI	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,584	TANEJA, RAJNEESH	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Claims 1-9 are pending in this action. Claims 1-9 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/611044. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed toward a composition comprising microgranules of a proton pump inhibitor coated enterically and a liquid suspension vehicle with a pH of less than 6.0. The co-pending application is directed toward the same composition comprising an acid labile drug. As a proton pump inhibitor

is an acid labile drug, the co-pending application and the instant application are related by a genus-species relationship. In that the '044 claims the genus (acid labile drug) and '584 claims the species (proton pump inhibitors).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by WO 02/45692.

WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension to be administered to a patient in need thereof. The reference teaches that it is known to coat these oral dosage forms of acid labile active ingredients with enteric coating (page 1). The particle size of the active agent is less than 2 mm, and preferably between 50-800 microns. Among the proton pump inhibitors listed was lansoprazole (page 1, and example 6, page 13). The reference teaches providing a juice or suspension for the oral administration of the acid labile active agent (page 2). The dosage form is in the form of a powder and prior to administration the active agent is combined with the liquid vehicle (page 3).

The reference teaches the composition has a viscosity sufficient to form a suspension because the reference teaches that the composition is made into a suspension. As the reference teaches the same composition it is the position of the examiner that the suspension would have the same pH as that claimed by Applicant. As Applicants themselves teach (page 4, lines 19-22) the composition may inherently have the desired pH of less than 6.0, and Applicant does not disclose specific examples of acidic excipients to add to the composition. The specification only discloses adding an acidifier but does not disclose what acidifier means. Since the Examples 6 and Example C teach the forming enterically coated microgranules and forming a suspension of the

microgranules it is the position of the examiner that the composition would have the desired pH and a viscosity sufficient to form a suspension. Example C discloses that uniform swelling is achieved. If the solution had not been at a pH of 6 or below, then the enterically coated microgranules would have been degraded and a solution would have formed. Thus the pH of the solution must be less than 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/45692.

WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension. The reference teaches that it is known to coat these oral dosage forms of acid labile active ingredients with enteric coating (page 1). The particle size of the active agent is less than 2 mm, and preferably between 50-800 microns. Among the proton pump inhibitors listed was lansoprazole (page 1, and example 6, page 13). The reference teaches providing a juice or suspension for the oral administration of the acid labile active agent (page 2). The dosage form is in the form of a powder and prior to administration the active agent is combined with the liquid vehicle (page 3).

Example 6 discloses a composition making microgranules of lansoprazole, and Example C discloses forming a suspension of these microgranules. Although the reference does not teach the pH requirements of less than 6.0 nor does it disclose what the viscosity of the suspension is that is formed in Example C, it would have been obvious to one of ordinary skill in the art to provide a suspension with the specific pH requirements such that the enterically coated microgranules would not dissolve in the liquid vehicle, but would form a suspension. As example C discloses that in the suspension a desirable swelling is achieved this would lead one of ordinary skill in the

art to expect that the solution is in a pH range sufficiently low to prevent the degradation of the enterically coated microgranules.

Although the reference does not teach the specific viscosity requirement it would be obvious to one of ordinary skill in the art to adjust the thickening ingredients in the composition to achieve the desired viscosity.

The reference does not specifically disclose a kit composition. However it does disclose first making the microgranules and then adding them to a liquid vehicle. It would have been obvious to one of ordinary skill in the art that the two components, the microgranules and the liquid vehicle would first need to be in separate containers before they are mixed. Thus a kit comprising two separate containers, one comprising the microgranules of acid labile active agent (proton pump inhibitor) and the other the liquid vehicle would be obvious to one of ordinary skill in the art.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/25070 in view of WO 02/45692.

WO '070 teaches a pharmaceutical composition for oral administration to animals comprising a proton pump inhibitor in the form of beads that are enterically coated and incorporated with a pH buffer into water or a water solution (claim 6). The pH buffer is used to decrease the pH of the solution to 5.5 or below (page 8). The proton pump inhibitor is lanzoprazole (claim 11). The reference also teaches making a kit comprising the dry enteric coated beads (claims 14, 15), and the enterically coated beads are added to a liquid vehicle, such as water.

The reference does not teach the viscosity requirement nor does it teach making microparticles of the proton pump inhibitor.

WO '692 cures this deficiency and is discussed in detail above. As discussed above, WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension to be administered to a patient in need thereof. The reference teaches that it is known to coat these oral dosage forms of acid labile active ingredients with enteric coating (page 1). The particle size of the active agent is less than 2 mm, and preferably between 50-800 microns.

One of ordinary skill in the art would be motivated to make microparticles because microparticles make a more uniform suspension. One of ordinary skill in the art would be motivated to make a solution with a viscosity that is suitable to form a suspension, and would thus look to WO '692 that teaches that by adding thickening agents the desired viscosity can be achieved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

GSKishore

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